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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,130	03/01/2001	Kakuji Torigoe	TORIGOE-4	8207

1444 7590 01/28/2004

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,130	TORIGOE ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- Th MAILING DATE of this communication appears on the cover sh t with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED OFFICE ACTION

Applicant's amendment filed on 30 October 2003 is acknowledged and entered. Following the amendment, claims 2, 8 and 9 are canceled, and claims 1, 5, 6 and 10 are amended.

Currently, claims 1, 3-7 and 10 are pending and under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 2, 8 and 9 are moot as applicants have canceled the claims.

The rejection of claims 1, 3-5 and 7 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendment.

Formal Matters:

Claim 5 is objected to for the following informalities, appropriate correction is required for each item:

The recitation of "nucleotide 35 to 485" in line 3 of the claim should be "nucleotide**s** 35 to 485".

New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 6 and 10 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth in the last Office Action, paper No. 14, at pages 3-4.

Applicants argument filed on 30 October 2003 has been fully considered, but is not deemed persuasive for reasons below.

With respect to claim 5, at pages 4-5 of the response, applicants argue that the specification discloses that a DNA of this invention usually comprises *a part* or the whole of the nucleotide sequence shown in SEQ ID NO:32, and applicants believe that this recitation contains DNA consisting of nucleotides 35-485 of SEQ ID NO:32, which is excluded from claim 5, in order to avoid the teachings of the prior art by Adams. This argument is not persuasive because, while applicants are trying to avoid the prior art, "a part" of SEQ ID NO:32 is not the same as nucleotides 35-485 of SEQ ID NO:32 as the scope of the two are very different, i.e., the former has much broader scope. As such, it cannot be used as a basis for the new limitation of "nucleotides 35-485 of SEQ ID NO:32" The specification has no support for this specific and narrower limitation. By reciting "nucleotides 35-485 of SEQ ID NO:32", the claim has changed the scope of the invention without support by the original disclosure, and therefore, it constitutes new matter.

With respect to claim 6, applicants argue, at pages 5 of the response, that the specification discloses that the human OL-18 BP has 61% sequence homology with the mouse IL-18 BP, and that the claim claims a DNA encoding IL-18 BP of human origin or the variants closer to human than mouse. This argument is not persuasive because, as addressed in the last Office Action, the specification discloses that the amino acid sequence homology between human and mouse IL-18 BP is about 61%, which is not an indication of an inventive concept, i.e., it does not indicate that a polypeptide having a homology of higher than 61% to the amino acid sequence of SEQ ID NO:1 is a IL-18BP, nor does it suggest a invention of a DNA encoding a polypeptide having a homology of higher than 61% to SEQ ID NO:1, and IL-18 binding activity. Further, a polypeptide having a sequence homology of 65% to SEQ ID NO:1, for example, can be still more closer to the mouse sequence of IL-18 BP than that of human IL-18 regarding its sequence homology.

The newly amended claim 10 recites "by digesting the polypeptide ..., said peptide fragment having an IL-18 binding activity". The specification discloses several specific fragments of the polypeptide resulted from trypsin digestion for the purpose of peptide mapping,

which is merely technical details for analytical purpose. The specification never suggests that these fragments have any functional property, nor were they never tested for their IL-18 binding activity. Therefore, they were not disclosed as being an inventive concept, and cannot serve as any basis for any purpose other than analytical peptide mapping. As such, the new recitation in the claim constitutes new matter.

Claim 1 and the dependent claims 3, 4 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly amended claim 1 recites "wherein said protein is not a protein encoded by a DNA consisting of nucleotides 35 to 485 of SEQ ID NO:32". Such a limitation constitutes new matter for the same reasons addressed above for claim 5. This is a new matter rejection.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth in the last Office Action mailed on 02 June 2003, and for the reasons below.

Claim 6 remains indefinite for the recitation of "a sequence homology *of* not higher than ..." in line 7. It is unclear what is meant.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 6 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to an IL-18 binding protein having SEQ ID NO:1, functional fragments thereof, and the DNA encoding SEQ ID NO:1, does not reasonably provide enablement for claims to [all IL-18 binding proteins which comprise small fragments of SEQ ID NO:1 (claims 2 and 10), and] DNA encoding the variants or homologues thereof (claims 5 and 6). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims, for the reasons set forth in the previous Office Actions, paper No. 12 and 14.

Applicants argument filed on 30 October 2003 has been fully considered, but is not deemed persuasive for reasons below.

At pages 6-7 of the response, applicants argue, with regard to claims 5 and 6, that Experiment 1-3 in the specification discloses the digestion of IL-18 BP with trypsin for peptide mapping, and the method for screening the polypeptide fragments of the present invention, and that said fragments can be easily screened out by testing their effect on the induction of IFN-γ production by human IL-18. This argument is not persuasive because it is irrelevant as claims 5 and 6 are not directed to the fragments of IL-18 BP.

Claims 5 and 6 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth in the previous Office Action, paper No. 12 and 14.

Applicants argument filed on 30 October 2003 has been fully considered, but is not deemed persuasive for the same reasons above, as applicants indicate, on page 7 of the response, that the same argument for the above rejection is applicable.

Note: the amendment of claims 1, 5, 6, and 10 raises new issues regarding enablement and written description in claims 1, 3-7 and 10, which are not addressed in the present Office

Action because the amendment of claims 1, 5, 6, and 10 constitutes new matter. However, the issues will be addressed if new matter rejection is removed.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 4 and 7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. for locus AA311795, and further in view of Sibson et al., WO94/01548, for the reasons set forth in the previous Office Action, paper No. 12, at page 8.

Applicants argument filed on 30 October 2003 has been fully considered, but is not deemed persuasive for reasons below.

At pages 7-8 of the response, applicants argue that because Adams's nucleotide sequence is now excluded from claims 1-4, it would not have been obvious to arrive at the present invention because Sibson merely discloses the desirability of generally placing a cDNA into an expression vector to express the encoded protein. This argument is not persuasive for the following reasons. As addressed in the previous Office Action, the polypeptide encoded by Adams's cDNA comprising nucleotides 35-485 of SEQ ID NO:32 would comprise amino acids 13-161 of SEQ ID NO:1 (164 amino acids) with 98% sequence similarity. It is highly likely that

said polypeptide would have inherently possess IL-18 binding activity as it comprises 88% of the sequence of SEQ ID NO:1 with 98% sequence similarity, which would qualify the polypeptide as "an IL-18 binding fragment" of SEQ ID NO:1.

The above rejection would be reinstated for claim 10 if new matter rejection of the claim is removed.

Conclusion:

No claim is allowed.

Advisory Information:

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
1/16/04